

## PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION  
(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark  
Office  
(Box PCT)  
Crystal Plaza 2  
Washington, DC 20231  
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 07 July 1999 (07.07.99)	
International application No. PCT/SE98/01717	Applicant's or agent's file reference 2988615
International filing date (day/month/year) 24 September 1998 (24.09.98)	Priority date (day/month/year) 23 October 1997 (23.10.97)
Applicant LAAKSO, Timo et al	

1. The designated Office is hereby notified of its election made:

in the demand filed with the International Preliminary Examining Authority on:

06 May 1999 (06.05.99)

in a notice effecting later election filed with the International Bureau on:

\_\_\_\_\_

2. The election  was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 36, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No.: (41-22) 740.14.35	Authorized officer F. Baechler  Telephone No.: (41-22) 338.83.38
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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 98/01717

## A. CLASSIFICATION OF SUBJECT MATTER

**IPC6: A61K 9/14, A61K 9/50, B01J 13/00**

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

**IPC6: A61K, B01J**

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

**SE,DK,FI,NO classes as above**

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**WPI, CAPLUS, EMBASE, USPATFULL**

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4384975 A (JONES W. FONG), 24 May 1983 (24.05.83), column 3, line 18 - column 6, line 9 --	1-22
A	US 4652441 A (CHIROAKI OKADA ET AL), 24 March 1987 (24.03.87), claims --	1-22
A	US 5407609 A (THOMAS R. TICE ET AL), 18 April 1995 (18.04.95), column 3, line 49 - column 7, line 27 --	1-22
A	US 4568559 A (ELIE S. NUWAYSER ET AL), 4 February 1986 (04.02.86), claims --	1-22

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:	
"A"	document defining the general state of the art which is not considered to be of particular relevance
"E"	earlier document but published on or after the international filing date
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O"	document referring to an oral disclosure, use, exhibition or other means
"P"	document published prior to the international filing date but later than the priority date claimed
"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X"	document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y"	document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&"	document member of the same patent family

Date of the actual completion of the international search

**12 February 1999**

Date of mailing of the international search report

**22 -02- 1999**Name and mailing address of the ISA/  
Swedish Patent Office  
Box 5055, S-102 42 STOCKHOLM  
Facsimile No. + 46 8 666 02 86

Authorized officer

**Anneli Jönsson**  
Telephone No. + 46 8 782 25 00

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 98/01717

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0052510 A2 (SYNTEX INC.), 26 May 1982 (26.05.82) -- -----	1-22

## INTERNATIONAL SEARCH REPORT

Information on patent family members

02/02/99

International application No.

PCT/SE 98/01717

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4384975 A	24/05/83	CH 648217 A,B DE 3121983 A FR 2484281 A,B GB 2077693 A,B JP 57027128 A US 4933105 A	15/03/85 04/02/82 18/12/81 23/12/81 13/02/82 12/06/90
US 4652441 A	24/03/87	BG 60493 B CA 1233414 A EP 0145240 A,B SE 0145240 T3 GR 80818 A HK 3792 A IE 57721 B JP 1057087 B JP 1761586 C JP 60100516 A LV 5755 A,B PT 79450 B US 4711782 A US 4917893 A US 5061492 A US 5476663 A US 5631020 A US 5631021 A	31/05/95 01/03/88 19/06/85  04/03/85 17/01/92 24/03/93 04/12/89 28/05/93 04/06/85 20/12/96 11/12/86 08/12/87 17/04/90 29/10/91 19/12/95 20/05/97 20/05/97
US 5407609 A	18/04/95	AT 133087 T AU 5741590 A CA 2050911 A,C CN 1047223 A DE 69024953 D,T DK 471036 T EP 0471036 A,B SE 0471036 T3 ES 2084698 T FI 915129 D GR 1000614 B GR 90100330 A HK 30897 A IE 69313 B IL 94296 A JP 2582186 B JP 4505454 T MX 20594 A NO 302683 B WO 9013361 A	15/02/96 29/11/90 05/11/90 28/11/90 14/08/96 28/05/96 19/02/92  16/05/96 00/00/00 31/08/92 10/10/91 21/03/97 04/09/96 31/10/95 19/02/97 24/09/92 31/03/94 14/04/98 15/11/90
US 4568559 A	04/02/86	US 4623588 A	18/11/86

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

02/02/99

International application No.  
PCT/SE 98/01717

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0052510 A2	26/05/82	SE 0052510 T3	
		AT 21624 T	15/09/86
		AU 556754 B	20/11/86
		AU 7756081 A	27/05/82
		CA 1176565 A	23/10/84
		HK 20489 A	17/03/89
		IE 52003 B	13/05/87
		JP 1901277 C	27/01/95
		JP 4040329 B	02/07/92
		JP 57118512 A	23/07/82
		MX 9202840 A	30/06/92
		US 4675189 A	23/06/87
		ZA 8107973 A	27/07/83

## PATENT COOPERATION TREATY

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2988615	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/SE98/01717	International filing date (day/month/year) 24.09.1998	Priority date (day/month/year) 23.10.1997
International Patent Classification (IPC) or national classification and IPC7 A 61 K 9/14, A 61 K 9/50, B 01 J 13/00		
Applicant BIOGLAN THERAPEUTICS AB et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:

- I  Basis of the report
- II  Priority
- III  Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV  Lack of unity of invention
- V  Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI  Certain documents cited
- VII  Certain defects in the international application
- VIII  Certain observations on the international application

Date of submission of the demand 06.05.1999	Date of completion of this report 09.12.1999
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88	Authorized officer Anneli Jönsson/Els Telephone No. 08-782 25 00

Form PCT/IPEA/409 (cover sheet) (January 1994)

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

International application No.

PCT/SE98/01717

**I. Basis of the report**

1. This report has been drawn on the basis of (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

 the international application as originally filed. the description, pages \_\_\_\_\_, as originally filed,

pages \_\_\_\_\_, filed with the demand,

pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_,

pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

 the claims, Nos. \_\_\_\_\_, as originally filed,

Nos. \_\_\_\_\_, as amended under Article 19,

Nos. \_\_\_\_\_, filed with the demand,

Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_,

Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_

 the drawings, sheets/fig \_\_\_\_\_, as originally filed,

sheets/fig \_\_\_\_\_, filed with the demand

sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_,

sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_

2. The amendments have resulted in the cancellation of:

 the description, pages \_\_\_\_\_ the claims, Nos. \_\_\_\_\_ the drawings, sheets/fig \_\_\_\_\_

3.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.

PCT/SE98/01717

**V. Resoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	<u>1-22</u>	YES
	Claims	_____	NO
Inventive step (IS)	Claims	<u>1-22</u>	YES
	Claims	_____	NO
Industrial applicability (IA)	Claims	<u>1-22</u>	YES
	Claims	_____	NO

**2. Citations and explanations**

The claimed invention relates to a method for encapsulating an active substance in a biodegradable polymer. The method comprises the steps of a) dissolving the biodegradable polymer in an organic solvent and b1) dispersing said active substance in the organic solution obtained in step a). A dispersion with the active substance as the inner phase thereof is provided, alternative to b1) involving the emulsifying of said active substance, dissolved in water or other aqueous solvent, in the organic solution obtained in step a). This provides an emulsion with the active substance as the inner aqueous phase thereof; c) subjecting the dispersion obtained in step b1) or the emulsion obtained in step b2) to an encapsulation operation with an aqueous polyethylene glycol solution as a continuous phase. Micro- or nanoparticles having the active substance encapsulated therein are obtained.

A method for preparing controlled or sustained release particles having a high entrapment of water-soluble substances is provided by this invention. Low energy mixing is also utilised. This is a convenient method for producing particles in micro or nano size. Previously used methods include the use of polyvinyl alcohol (PVA) and other surfactants. These undesired compounds are not necessary used in the claimed method.

US 4 384 975 A discloses how to form microspheres. The method is based on solvent removal from an oil-in-water emulsion. The initial removal of solvent causes the polymer to precipitate in a viscous liquid state and envelop the solid drug particles.

..../....

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: V

Another document disclosing a method for solvent evaporation is US 4 652 441 A. This document discloses a water-in-oil composition comprising the active agent in the water phase and the polymer substance in the oil phase. Particles are formed after treatment and the solvent is desorbed from the oil phase. None of these documents disclose the claimed invention using polyethylene glycol as a continuous medium. Therefore, the documents cited above only disclose the general state of the prior art.

Document US 5 407 609 A discloses a method for microencapsulating an agent. The method comprises the steps of: a) dissolving or dispersing the active agent in a solvent, containing the wall-forming material, b) the dispersion from a) is combined with a continuous process medium, c) after formation of the emulsion in b), an extraction medium to extract the solvent is added. Microencapsulated product is formed. The document does not disclose the claimed invention's use of polyethylene glycol as a continuous medium. Therefore, the document only discloses the general state of the prior art.

Document US 4 568 559 discloses a method for preparing coated microparticles comprising medicaments. Particles comprising the active component are coated with a film-forming polymer in a fluidized bed. The polymer can be a polylactide, a polyglycolide or a copolymer of lactide and glycolide. However, the document does not disclose the claimed method or the use of polyethylene glycol as in the claimed method. Thus the document only discloses the general state of the prior art.

EP 52 510 A2 discloses the preparation of a pharmaceutical composition comprising a drug (such as a protein) and a polymer such as a poly (lactide-co-glycolide) copolymers. The method comprises dispersing an aqueous solution containing the polypeptide with a polymer hydrolysis-modifying agent in an organic solvent containing the encapsulating polymer. The formed particles are hardened, collected, washed and dried. The document does not disclose the claimed process. The document only discloses the general state of the prior art.

Consequently, the claimed invention according to claims 1-22 fulfills the requirements of novelty, inventive step and industrial applicability.

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2988615	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/SE98/01717	International filing date (day/month/year) 24.09.1998	Priority date (day/month/year) 23.10.1997
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Date of submission of the demand  06.05.1999	Date of completion of this report  09.12.1999
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88	Authorized officer Telex 17978 PATOREG-S Anneli Jönsson/Els Telephone No. 08-782 25 00

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

International application No.

PCT/SE98/01717

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pages \_\_\_\_\_, filed with the demand,  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_ the claims, Nos. \_\_\_\_\_, as originally filed,  
Nos. \_\_\_\_\_, as amended under Article 19,  
Nos. \_\_\_\_\_, filed with the demand,  
Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_  
Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_ the drawings, sheets/fig \_\_\_\_\_, as originally filed,  
sheets/fig \_\_\_\_\_, filed with the demand  
sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_  
sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/SE98/01717**V. Resoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

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	Claims		NO
Inventive step (IS)	Claims	1-22	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-22	YES
	Claims		NO

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US 4 384 975 A discloses how to form microspheres. The method is based on solvent removal from an oil-in-water emulsion. The initial removal of solvent causes the polymer to precipitate in a viscous liquid state and envelop the solid drug particles.

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE98/01717

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: V

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Document US 4 568 559 discloses a method for preparing coated microparticles comprising medicaments. Particles comprising the active component are coated with a film-forming polymer in a fluidized bed. The polymer can be a polylactide, a polyglycolide or a copolymer of lactide and glycolide. However, the document does not disclose the claimed method or the use of polyethylene glycol as in the claimed method. Thus the document only discloses the general state of the prior art.

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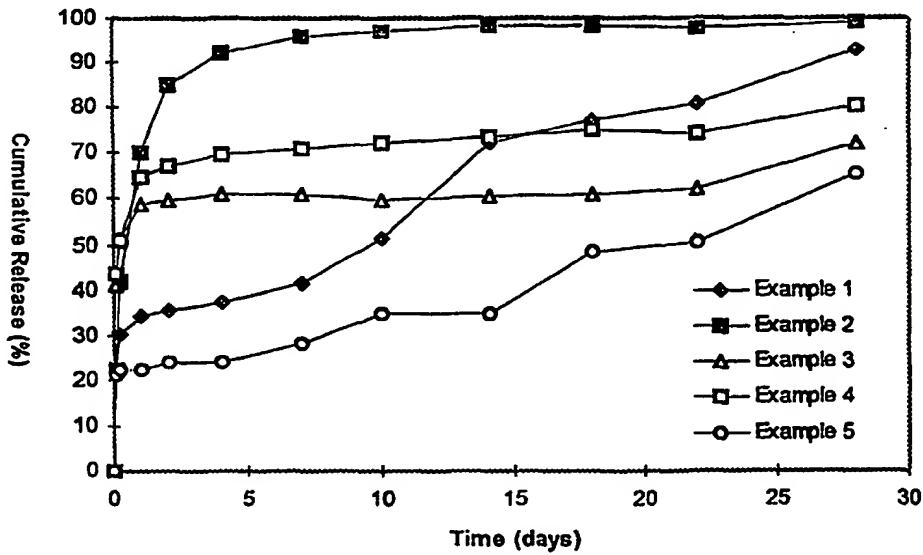
Consequently, the claimed invention according to claims 1-22 fulfils the requirements of novelty, inventive step and industrial applicability.



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : <b>A61K 9/14, 9/50, B01J 13/00</b>	A1	(11) International Publication Number: <b>WO 99/20253</b> (43) International Publication Date: 29 April 1999 (29.04.99)
(21) International Application Number: PCT/SE98/01717		(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
(22) International Filing Date: 24 September 1998 (24.09.98)		
(30) Priority Data: 9703874-9 23 October 1997 (23.10.97) SE		
(71) Applicant ( <i>for all designated States except US</i> ): BIOGLAN THERAPEUTICS AB [SE/SE]; P.O. Box 50310, S-202 13 Malmö (SE).		
(72) Inventors; and		
(75) Inventors/Applicants ( <i>for US only</i> ): LAAKSO, Timo [SE/SE]; Boltensternsväg 33D, S-236 38 Höllviken (SE). RESLOW, Mats [SE/SE]; Bondevägen 45, S-227 38 Lund (SE).		
(74) Agent: AWAPATENT AB; P.O. Box 45086, S-104 30 Stockholm (SE).		

## (54) Title: ENCAPSULATION METHOD



## (57) Abstract

A novel method of encapsulating an active substance in a biodegradable polymer, which comprises: a) dissolving said biodegradable polymer in an organic solvent therefor; b<sub>1</sub>) dispersing said active substance in the organic solution obtained in step a), to provide a dispersion with the active substance as the inner phase thereof; or alternatively b<sub>2</sub>) emulsifying said active substance, dissolved in water or other aqueous solvent therefor, in the organic solution obtained in step a), to provide an emulsion with the active substance as the inner aqueous phase thereof; and c) subjecting the dispersion obtained in step b<sub>1</sub>), or alternatively the emulsion obtained in step b<sub>2</sub>), to an encapsulation operation with an aqueous polyethylene glycol solution as a continuous phase, to provide micro- or nanoparticles having the active substance encapsulated therein. Sustained release particles obtainable therefrom.

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
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